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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/150,813	09/11/1998	DAVID J. GRAINGER	295.027US1	6933
21186	7590	12/17/2003	EXAMINER	
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402			MURPHY, JOSEPH F	
			ART UNIT	PAPER NUMBER
			1646	
DATE MAILED: 12/17/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/150,813	GRAINGER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Joseph F Murphy	1646	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 September 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 63-65,67-69,71-73 and 75-83 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 63-65,67-69,71-73 and 75-83 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                              | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>09292003</u> | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Formal Matters***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/29/2003 has been entered.

Claims 63-65, 67-69, 71-73, 75-83 are pending and under consideration.

### ***Declaration***

The Declaration filed under 37 CFR 1.132 on 9/29/2003 is acknowledged, and will be addressed, *infra*.

### ***Claim Rejections - 35 USC § 112 first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 63-65, 67-69, 71-73, 75-83 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inhibiting leukocyte migration by administration to a mammal an effective amount of SEQ ID NO: 1, 7, 14, 38, 40-44, 65-68, 72-74, and the reverse D sequences listed in claim 67, does not reasonably provide enablement for a method of preventing or inhibiting an indication of a chemokine induced activity, or an indication associated with leukocyte migration by administration of the peptides, or a method of preventing or inhibiting an indication associated with hematopoietic cell recruitment, a method

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to enhance or increase hematopoietic cell-associated activity at a tumor site, or a method to modulate the chemokine induced activity of hematopoietic cells at a preselected physiological site. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

In the instant case, the claims are directed to the prevention or inhibition of indications associated with either leukocyte migration or hematopoietic cells recruitment. The Specification teaches that chemokines are associated with the inflammatory response (page 30, lines 26-29), and discloses examples of the effect of the peptide 3 sequence on the inhibition of THP-1 cell migration (page 134, Table 4). Applicant has provided insufficient guidance to enable one of ordinary skill in the art to determine, without undue experimentation, how to practice a method of prevention of indications associated with leukocyte migration or hematopoietic cell recruitment. In order for the skilled artisan to practice a method of prevention of the indication by administration of the peptides, the skilled artisan would have to know how to identify a mammal which was definitely going to develop the indication before the development occurred, and administer the peptide before the indication had developed. The Declaration submitted under 37 CFR 1.132 argues (Dec at 4, paragraph 11) that administration of the peptides prior to manifestation of clinical symptoms of an indication in which inappropriate inflammation is a contributory factor can prevent the underlying pathogenesis or clinical symptoms of the indication. However, the case in which the peptides are administered prior to clinical manifestation is not a prevention of the indication, it is only a prevention of the clinical manifestation, the indication has already occurred. There is not adequate guidance as to the

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methods necessary to know an animal will develop an indication and to administer the peptide prophylactically. This is merely an invitation to the skilled artisan to use the current invention as a starting point for further experimentation. Applicants do not disclose any actual or prophetic examples of methods wherein mammals known to develop an indication of leukocyte or hematopoietic cell recruitment were identified and the indication was prevented by administration of the peptides.

Additionally, the claims are directed to the prevention or inhibition of indications associated with hematopoietic cell recruitment. It is known in the art (Fundamental Immunology, Fourth Edition, 1999, Paul, William ed. Lippincott-Raven, Philadelphia, PA, pages 184-185) that hematopoietic cells are derived from intraembryonic mesoderm, and that hematopoietic stem cells, derived from hematopoietic cells form in to T-, B- or myeloid-cells, as well as erythroid cells (see page 184, column 2, first paragraph, and page 185, Figure 1). The Specification teaches that chemokines are associated with the inflammatory response (page 30, lines 26-29), and discloses examples of the effect of the peptide 3 sequence on the inhibition of THP-1 cell migration (page 134, Table 4). Applicant has provided insufficient guidance to enable one of ordinary skill in the art, without undue experimentation to practice a method of preventing or inhibiting indications associated with hematopoietic cell recruitment by administration of the peptide 3 derivatives since the Specification is only enabling for methods of inhibiting leukocyte migration by administration to a mammal an effective amount of the peptide 3 derivatives. Although the specification discloses the inhibition of THP-1 cell migration by peptide 3 and derivatives, there is not a nexus between the inhibition of the THP-1 cells and any effect on any and all other hematopoietic cells. The 1.132 declaration sets forth (Dec at 2,

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paragraph 4) that chemokines are central regulators of leukocyte recruitment or migration, and thus the specification is enabling for methods wherein leukocyte migration is inhibited with the derivatives of peptide 3 set forth in the claims. However, the nexus between the demonstrated action of the peptide 3 derivatives on leukocyte migration, and the recruitment of any and all hematopoietic cells is not disclosed in the specification, and is an invitation to the artisan to use the current invention as a starting point for further experimentation. Applicants do not disclose any actual or prophetic examples of the inhibition of recruitment of hematopoietic cells other than the inhibition of leukocyte migration.

Given the breadth of claims 63-65, 67-69, 71-73, 75-83 in light of the predictability of the art as determined by the number of working examples, the level of skill of the artisan, and the guidance provided in the instant specification and the prior art of record, it would require undue experimentation for one of ordinary skill in the art to practice the claimed invention.

### ***Conclusion***

No claim is allowed.

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***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245.


The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Joseph F. Murphy, Ph. D.  
Patent Examiner  
Art Unit 1646  
December 9, 2003



YVONNE EYLER, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600